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REMARKS

The Applicant requests that the Examiner enter the amendment prior to examining the application.

Claims 60-68, 70-75, and 83-86 remain pending in the application upon entry of this response. Claims 60-68 and 70-75 stand rejected by the Examiner. Claims 54-59 have been cancelled without prejudice by the Applicant, and claims 83-86 have been added. Please reconsider the claims for the reasons presented below.

Claims 61-65, 67-69, and 70-75 have been amended to correct matter of form. Claim 66 has been amended to clarify implicit aspects of the invention. These amendments are not in response to the cited prior art or directed to the patentability of the invention; therefore the amendment is not intended to narrow the claims or otherwise limit the scope of equivalents thereof. Entry of these amendments and reconsideration of the claims is respectfully requested.

Claims 60-68 and 70-75 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/01221 (hereinafter *Hanna 1*). The Examiner asserts that *Hanna 1* discloses the subject matter as described in claims 60-68 and 70-75. The Applicant respectfully traverses the rejection.

In the Advisory action dated May 17, 2006, the Examiner asserts that the declaration of Dr. Andreas Kordikowski, filed April 24, 2006, is deficient to overcome the rejection. The Examiner deemed the estimates of crystallinity to be matter of opinion with no factual basis. The Examiner also objected to the legends not clearly identifying the several plots found on the attached graphs. In response, the Applicant respectfully submitted on July 24, 2006, a declaration under 37 CFR § 1.132 of Peter York, Ph.D. to the Office. Because the declaration as received by the Office lacked quality due to a poor facsimile transmission, a more clear copy of this declaration is submitted with this response. In item 5 of the declaration, Dr. York describes the expected XRPD plots of amorphous compounds (plot A of Figure 1) and crystalline compounds (plot B of figure 1) and the differences between these plots. The plots and legends have been marked with letters in order to clearly identify the plots. Dr. York further describes the XRPD

PAGE 8/15 * RCVD AT 9/22/2006 7:04:48 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/21 * DNIS:2738300 * CSID:7136234846 * DURATION (mm-ss):03-46

plots for a compound co-formulated with a polymer in various stages from highly crystalline to totally amorphous (plots D through A of Figure 2). In item 6, Dr. York compares the plots of Figures 35, 36, 45, and 46 of *Hanna 1* with the plots of Figures 1 and 2 of the declaration. Based on the comparison of these figures, Dr. York factually concludes that at least half of the Salmeterol Xinafoate disclosed in examples 10 and 16 of *Hanna 1* is present in a crystalline form.

Thus, *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% w/w and about 100% w/w of the active substance is present in an amorphous form, as recited by claim 60. Having presented sufficient evidence as to the crystallinity of the active substance in *Hanna 1*, Applicant respectfully requests withdrawal of the rejection.

Claim 60 was previously rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hanna 1* in view of Publication No. U.S. 2004/0071783 A1 to *Hanna et al.* (hereinafter *Hanna 2*). The Applicant respectfully traverses the rejection.

The combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest all the elements of claim 60. The Examiner relies on *Hanna 2* for teaching that it is known to use ketoprofen in a process utilizing SEDS, and further states it would have been obvious to one of ordinary skill in the art to use the ketoprofen of *Hanna 2* in the *Hanna 1* SEDS process. However, even after combining *Hanna 2* with *Hanna 1*, the combination does not teach, show, or suggest all the elements of claim 60.

The combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% and about 100% of the active substance is present in an amorphous as opposed to crystalline form. As described above, at least half of the active compound of *Hanna 1*, salmeterol xinafoate, is present in a crystalline form. In addition, the active compounds in *Hanna 2* are also present in a crystalline form. (See, e.g., paragraph [0111], ibuprofene; paragraph [0116] and paragraph [0117], both salicylic acid.) Because both *Hanna 1* and *Hanna 2* teach active compounds which are present in highly crystalline forms, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation in which between about 90% and about 100% of the active substance is

PAGE 9/15 * RCVD AT 9/22/2006 7:04:48 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/21 * DNIS:2738300 * CSID:7136234846 * DURATION (mm-ss):03-46

present in an amorphous as opposed to crystalline form, as recited by claim 60. Withdrawal of the rejection is respectfully requested.

In conclusion, the references cited by the Examiner in the Final Office Action, alone or in combination, do not teach, show, or suggest the claimed invention. The Applicant respectfully submits that the claims are in condition for allowance and respectfully requests that the claims be allowed.

Respectfully submitted,

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PAGE 10/15 * RCVD AT 9/22/2006 7:04:48 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/21 * DNIS:2738300 * CSID:7136234846 * DURATION (mm-ss):03-46